UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,396	04/12/2004	Marcus B. Jones	05986/100M724-US1	3661

7278 7590 03/20/2007

DARBY & DARBY P.C.
P. O. BOX 5257
NEW YORK, NY 10150-5257

EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,396	JONES ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *11-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *42905 & 12105*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election

1) Acknowledgment is made of Applicants' election filed 12/27/06 in response to the restriction requirement mailed 12/06/06. Applicants have elected invention I, claims 1-10. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

Status of Claims

2) Claims 1-69 are pending.

Claims 11-69 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 1-10 are under examination. A First Action on the Merits is issued for these claims.

Sequence Listing

3) The raw sequence listing submitted in this application has been entered on 04/21/2004.

Information Disclosure Statements

4) Acknowledgment is made of Applicant's Information Disclosure Statements filed 04/29/05 and 01/21/05. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Priority

5) This instant application claims priority to the provisional applications, 60/462,254 and 60/462,255, both filed 04/11/03.

Specification - Informalities

6) The specification of the instant application is objected to for the following reason:

(a) The amino acid sequences depicted in Figure 4 are four amino acids or longer in length. Yet except for one amino acid sequence in Figure 4, the rest of the sequences are not identified by specific SEQ ID numbers as required under 37 C.F.R 1.821 through 1.825. Any sequences recited in the instant specification, which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply

with the requirements of 37 C.F.R 1.821 through 1.825. Note that branched sequences are specifically excluded from this definition.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g).

(b) The use of trademarks has been noted in this application. For example, see line 1 of page 30 for 'Tween 80'. See page 31 for 'Fast-Flo', 'Emdex', 'Emcompress', 'Avicell', and 'Explotab'. See line 2 of page 32 for 'Carbowax'. Each trademark recitation must be capitalized. Although the use of trademarks is permissible in patent applications, the propriety nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification and make necessary changes wherever trademark recitations appear.

(c) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See line 12 on page 39 and first paragraph under Example 1 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Rejection(s) under 35 U.S.C. § 101

7) 35 U.S.C. § 101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

8) Claim 8 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Claim 8, as written, does not sufficiently distinguish over a host cell as it exists naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. The claimed host cell is not an 'isolated host cell'. In view of the contemplation within the instant specification at pages 12 and 15 of a host cell comprising a vector comprising the nucleotide sequence, the claimed host cell reads on a human

vaccinated with a DNA vaccine expressing an antigenic determinant of LuxS polypeptide. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980)*. The claim(s) should be amended to indicate the hand of the inventor, e.g., by insertion of --An isolated-- as taught at page 41 of the instant specification. See MPEP 2105.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (Written Description)

9) The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10) Claims 1, 2, 5 and those dependent therefrom are rejected as are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Instant claims encompass an isolated nucleic acid molecule encoding a polypeptide comprising an amino acid sequence that is at least 90% identical to the amino acid sequence of SEQ ID NO: 2 (i.e. a polypeptide variant), or an isolated nucleic acid molecule comprising a nucleotide sequence that is at least 80% identical to the nucleotide sequence of SEQ ID NO: 1 (i.e., a nucleic acid variant). The genus of nucleic acid molecules so claimed are not associated with a specific function in the claims. The specification however contemplates prophylactic and therapeutic applications. However, the instant specification fails to teach a single nucleic acid variant encoding a polypeptide comprising an amino acid sequence that is at least 90% identical to the amino acid sequence of SEQ ID NO: 2 and a nucleic acid molecule variant comprising a nucleotide sequence that is at least 80% identical to the nucleotide sequence of SEQ ID NO: 1 and each concurrently having prophylactic and therapeutic effects. The prophylactic and therapeutic applications minimally require a specific interaction of the encoded polypeptide with a compound. The precise structure or relevant identifying characteristics of nucleic acid molecule that encodes a polypeptide having 90% identity to the amino acid sequence of SEQ ID NO: 2 and the prophylactic and

therapeutic effects can be determined empirically by actually making DNA molecules that encode the polypeptides of the recited variability, and testing the varied DNA molecules to determine whether they encode the at least 90% modified polypeptide variants having the particularly disclosed therapeutic and prophylactic activity. The same applies to the nucleic acid of at least 80% identity to the reference nucleotide sequence of SEQ ID NO: 1. The *Written Description Guidelines* state:

> There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a wellestablished correlation between the structure and function in the art, one skilled in the art will be ableto reasonably predict the complete structure of the claimed invention from its function.

A mere statement that the invention includes an isolated nucleic acid that encodes a polypeptide having at least 90% identity to the amino acid sequence of SEQ ID NO: 12, or an isolated nucleic acid comprising a nucleotide sequence of at least 80% identity to a reference nucleotide sequence of SEQ ID NO: 1 is insufficient to meet the adequate written description requirement of the claimed invention. The polypeptide of SEQ ID NO: 2 or the nucleic acid molecule of SEQ ID NO: 1 has specific biologic properties. The polypeptide of SEQ ID NO: 2 has particular biologic properties dictated by the structure of the polypeptide and the corresponding structure of the structural gene sequence which encodes it. A convincing structure-function relationship has to exist between the structure of the gene sequence, the structure of the polypeptide encoded, and the function of the encoded polypeptide. The function cannot be predicted from the modification of the structure of the gene and in the instant case, the nucleic acid molecule encoding the at least 90% modified polypeptide variant. Applicants have not shown that variation or modification of the reference nucleotide sequence encoding a reference polypeptide as claimed would automatically predict the production of the polypeptide variant having the prophylactic and therapeutic activity. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of nucleic acid molecules encoding a representative number of species of polypeptide variants of at least 90% sequence identity as recited, sufficient to allow one skilled in the art to determine that the inventors had possession of the invention as claimed. The only isolated nucleic acid molecule species that is adequately described within the instant specification is the nucleic acid molecule comprising or consisting of the nucleotide sequence of SEQ ID NO: 1 which

encodes the polypeptide of SEQ ID NO: 2. With the exception of an isolated nucleic acid molecule encoding the polypeptide of SEQ ID NO: 2, a skilled artisan cannot envision the detailed chemical structure of all the nucleic acid molecule species encompassed by the claimed genus. Regardless of the complexity or simplicity of the method of isolation, conception cannot be achieved until reduction to practice has occurred. The specification does not describe the structural features commonly possessed by members of the genus that distinguish them from others. The instant specification fails to provide the complete structure of a representative number of nucleic acid variant species common to the members of the claimed genus which constitute a substantial portion of the genus wherein the variant species are usable in prophylactic and therapeutic applications described in the specification. Adequate written description requires more than a mere statement that it is a part of the invention and a reference to a potential method of isolating it. The nucleic acid variant itself is required. See *Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993)* and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.*

Rejection(s) under 35 U.S.C. § 112, First Paragraph (Scope of Enablement)

11) Claims 1, 2, 5 and 8-10 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule comprising or consisting of the nucleotide sequence of SEQ ID NO: 1 which encodes a polypeptide having the amino acid sequence of SEQ ID NO: 2, an expression vector comprising the same, and an isolated host cell comprising the expression vector, does not reasonably provide enablement for an isolated nucleic acid molecule (i.e., a variant) which encodes a polypeptide comprising an amino acid sequence that is at least 90% identical to the amino acid sequence of SEQ ID NO: 2, or for an isolated nucleic acid molecule (i.e., a variant) comprising a nucleotide sequence that is at least 80% identical to the nucleotide sequence of SEQ ID NO: 1, as claimed broadly. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims.

Instant claims are evaluated based on *Wands* factors. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- The quantity of experimentation necessary (time and expense);
- The amount of direction or guidance presented;

- The presence or absence of working examples of the invention;
- The nature of the invention;
- The state of the art;
- The relative skill of those in the art;
- The predictability or unpredictability of the art; and
- The breadth of the claims.

Claim 2 depends from claim 1 and is drawn to an isolated nucleic acid molecule encoding a polypeptide comprising an amino acid sequence that is at least 90% identical to the amino acid sequence set forth in SEQ ID NO: 2. The claimed nucleic acid molecule thus encompasses nucleic acid variants encoding polypeptide variants each comprising an amino acid sequence that is at least 90%, 92%, 94%, 96%, 98% or 99% identical to SEQ ID NO: 2. This means that the polypeptide variant encoded by the claimed nucleic acid molecule is up to 10% non-identical to SEQ ID NO: 2. Claim 5 depends from claim 1 and is drawn an isolated nucleic acid molecule comprising a nucleotide sequence that is at least 80% identical to the nucleotide sequence set forth in SEQ ID NO: 1. The claimed nucleic acid molecule thus encompasses nucleic acid variants each comprising a nucleotide sequence that is 80%, 85%, 90%, 95%, or 99% identical to the nucleotide sequence set forth in SEQ ID NO: 1. This means that the claimed nucleic acid molecule variant is up to 20% non-identical to SEQ ID NO: 1. As claimed currently, the claimed nucleic acid molecules or the recited polypeptide are not associated with any function. The instant specification however indicates prophylactic and therapeutic applications for the claimed variants, which are required to have the ability to elicit prophylactic and therapeutic effects against homologous or heterologous strain(s) of *Bacillus anthracis*. The showing in the instant specification however is limited to isolation of a *Bacillus anthracis* LuxS nucleic acid molecule that encodes a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2 which is speculated to elicit antibodies that inhibit or antagonize the activity of the *Bacillus anthracis* LuxS polypeptide. For example, see pages 15, 19-21, 24 and 25; and Examples 1, 4 and 9. However, outside this scope, there is not one single showing within the instant specification that a polypeptide variant that is at least 10% non-identical to SEQ ID NO: 2 which is encoded by the claimed nucleic acid variant would retain one or more linear or conformational epitopes therein and would have the ability to elicit prophylactic and therapeutic effects against any strain(s) of *Bacillus anthracis*. There is no showing that a polypeptide having 90% identity to SEQ ID NO: 2, if produced, would elicit antibodies that would

have the capacity to inhibit or antagonize the activity of the LuxS polypeptide produced by homologous or heterologous strains of *Bacillus anthracis.* There is no showing that an isolated nucleic acid molecule having 20% non-identity to SEQ ID NO: 1, if produced, would encode a polypeptide variant that would have the ability to elicit prophylactic and therapeutic effects against any strain(s) of *Bacillus anthracis* or would elicit antibodies that would have the capacity to inhibit or antagonize the activity of the LuxS polypeptide produced by homologous or heterologous strains of *Bacillus anthracis in vitro* or *in vivo*. There is no showing that the polypeptide variants encoded by the nucleic acid variants that are encompassed within the scope of the claims tolerate modifications and remain antigenic and retain the ability to elicit an antibody that inhibits or antagonizes the activity of the LuxS polypeptide produced by homologous or heterologous strains of *Bacillus anthracis in vitro* or *in vivo*. The instant specification does not provide the precise structure of the claimed variants. With this lack of showing and guidance, the Office would look into the literature in the relevant art of polypeptide variants encoded by nucleic acid variants in order perform the required *Wands* analysis.

With regard to the structure-function relationship of an encoded amino acid sequence in general, Rudinger *et al.* (*In*: *Peptide Hormones*. (Ed) JA Parsons, University Park Press, pages 1-7, June 1976) taught that 'the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study' (see page 6). Rudinger *et al.* further taught that 'it is impossible to attach a unique significance to any residue in a sequence' and that a 'given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence (see page 3). The lack of guidance within the instant specification in combination with Rudinger's teachings supports the Office's position regarding the unpredictability factor and the need to engage in considerable amount of undue experimentation.

The state of the art on microbial polypeptides in general indicates that a random replacement affecting the epitopic amino acid positions that are critical to the three-dimensional conformational structure and specific binding property of a protein, would result in a polypeptide that may be non-functional, or not optimally antigenic as a diagnostic reagent, or not optimally immunogenic as a vaccine candidate, because such positions tolerate no or little modifications. For

instance, Houghten *et al.* (New Approaches to Immunization, *Vaccines86*, Cold Spring Harbor Laboratory, p. 21-25, 1986) teach the criticality of individual amino acid residues and their positions in peptide antigen-antibody interactions. Houghten *et al.* state (see page 24):

> One could expect point mutations in the protein antigen to cause varying degrees of loss of protection, depending on the relative importance of the binding interaction of the altered residue. A protein having multiple antigenic sites, multiple point mutations, or accumulated point mutations at key residues could create a new antigen that is precipitously or progressively **unrecognizable by any of the antibodies** in the polyclonal pool. [Emphasis added].

Thus, it has already been established in the state of the art that variations in critical residues at specific positions of an amino acid sequence encoded by a nucleic acid variant could result in a polypeptide variant, which may induce an antibody that may *not* recognize or bind to the native polypeptide of a microorganism. There is no predictability that a polypeptide variant having up to 10% sequence non-identity with the native polypeptide of SEQ ID NO: 2 would remain antigenically immunospecific to homologous or heterologous isolates of *Bacillus anthracis.* The above-cited references reasonably demonstrate that even a single amino acid substitution/deletion will often dramatically affect the immunospecific biological activity or characteristics of a protein or polypeptide. Clearly, with up to 10% or 20% sequence non-identity to the polypeptide of SEQ ID NO: 2, the *Bacillus anthracis*-specific antigenic function of the recited polypeptide variant encoded by the claimed nucleic acid variant cannot be predicted, merely based on the sequence homology with the reference sequence, nor would it be expected to be nearly the same as that of the polypeptide of SEQ ID NO: 2. Although a skilled artisan might envision making a number of changes in the nucleic acid sequence of SEQ ID NO: 1 that encodes the reference polypeptide sequence of SEQ ID NO: 2 in accordance with Applicants' disclosure, it is highly uncertain or unpredictable that the polypeptide variant as recited would retain the ability to bind to an antibody that inhibits or antagonizes the activity of the LuxS polypeptide produced by homologous or heterologous strains of *Bacillus anthracis in vitro* or *in vivo*. If one nucleotide base in the nucleotide sequence that encodes the polypeptide of SEQ ID NO: 2 is deleted or inserted at a single position within the coding sequence, all the codons downstream of that insertion or deletion would be frame-shifted. If that frame-shift took place near the 5' end of the gene, it is likely that the varied polypeptide expressed will have little in common structurally or functionally with the native

polypeptide that comprises SEQ ID NO: 2. The polynucleotide variants isolated solely based on percent identity or homology do not predictably display the functions of the native molecules, absent an independent showing that the variant nucleic acid sequence produces a polypeptide variant that functions as desired. The antigenic or binding and antagonizing functions of a gene product based solely on percent sequence identity is unreliable and unpredictable, absent a supportive showing by production of a representative number of 20 to 10% non-identical polypeptide variant species that have the required prophylactic and therapeutic functions and the ability to bind to an antibody that inhibits the activity of the LuxS polypeptide of *Bacillus anthracis*. It should be noted that predictability or unpredictability is one of the *Wands* factors for enablement. The precise structural composition of the claimed nucleic acid that encodes the recited polypeptide variant having the above-identified functions is not disclosed, without which one of ordinary skill in the art cannot make and use the claimed product without undue experimentation. One simply cannot predict what effects a given deletion, insertion or modification in the nucleotide sequence would cause, and therefore such modified molecules are not enabled as Applicants' invention. Applicants have not enabled the full scope of the invention as claimed for those nucleic acid molecules which are altered or varied. The specification only discloses an isolated nucleic acid molecule that encodes a polypeptide of SEQ ID NO: 2. Undisclosed and unidentified nucleic acid variants encoding polypeptide variants of at least 20% or 10% identity to SEQ ID NO: 2 that are currently encompassed in the claims are not enabled for their full scope. For the reasons delineated above, making and using of the instantly claimed nucleic acid variant that encodes the recited polypeptide variant having the desired functions is well outside the realm of routine experimentation. Accordingly, undue experimentation would have been required by one of ordinary skill in the art at the time of the effective filing date of the instant application to reproducibly practice the invention as claimed, due to the lack of specific guidance, the lack of enabling disclosure, the art-demonstrated functional unpredictability as reflected in the state of the bacterial or microbial polypeptide art, the breadth of the claims, and the quantity of experimentation necessary. The claims are viewed as not meeting the scope of enablement provisions of 35 U.S.C § 112, first paragraph.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

12) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

13) Claims 2 and 8-10 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 2 is vague and indefinite in the limitation: 'nucleic acid molecule of claim 1 which encodes a polypeptide'. Claim 2 depends from claim 1 which is already recited as encoding 'a .... polypeptide'. Is the 'polypeptide' recited in claim 2 a different polypeptide than the one recited in claim 1?

(b) Claims 8-10, which depend directly or indirectly from claim 2, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

14) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15) Claims 1 and 8-10 are rejected under 35 U.S.C § 102(b) as being anticipated by Bourgogne *et al.* (In: *Abstracts of the 101st General Meeting of the American Society for Microbiology*, Orlando, FL, USA, page 127, 20-24 May 2001– Applicants' IDS).

Bourgogne *et al.* taught the isolated *luxS* gene of *B. anthracis* that expresses a polypeptide having AI-2 activity and a recombinant *E. coli* host cell expressing the polypeptide. The prior art recombinant *E. coli* host cell comprising the *luxS* gene of *B. anthracis* is expected to contain a vector. See the entire document.

Claims 1 and 8-10 are anticipated by Bourgogne *et al.*

Remarks

16) Claims 1-10 stand rejected.

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

18) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

March, 2007

S. DEVI, PH.D.
PRIMARY EXAMINER